K 123684

510(k) Summary
(As required by 21 CFR 807.92(a))

MAY 0 8 2013

Summary of Safety and Effectiveness for the Safety Needle

Date Prepared: January 31, 2013

A. Submitter Information

Sol-Millennium Medical, Inc.
5415 Sugarloaf Parkway
Suite 2203
Lawrenceville, GA 30043

Phone Number: 949-433-3058
Fax Number: 760-295-4381

Trade Name: Sol-Care Safety Needle

B. Device Information

Trade/Proprietary Name:	Sol-Care Safety Needle
Common name of device:	Hypodermic Needle
Classification Name:	Needle, Hypodermic, Single Lumen
Product Code:	80 FMI
Regulatory Class:	II
Classification Number:	880.5570
Reason for 510(k):	Significant modification of device previously found equivalent (Expanded intended use to include the addition of a safety feature)

C. Predicate Device: BD Eclipse Hypodermic Needle

Predicate 510(k) #:	K010188
Predicate product code:	FMI

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D. Device Description

The Sol-Care Safety Needle is a sterile, single use, standard hypodermic needle with a shield to enclose the needle after use. The device is available in 18 to 30 gauge and in lengths from 3/8" to 1-1/2". In addition, the needle tip is available in a regular bevel.

The Sol-Care Safety Needle has a shield that covers the needle point after use. In the activated position, the needle shield guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

The Sol-Care Safety Needles are sterilized by Ethylene Oxide Gas and supplied sterile in blister pack. One hundred blister packs are packaged in a chipboard box. Each Blister pack and chipboard box is labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.

E. Statement of Indications for Use

The Sol-Care Hypodermic Needle is used for general purpose injection and aspiration of fluids from vials, ampules and parts of the body below the surface of the skin.

The Sol-Care Hypodermic Needle contains a mechanism that covers the needle point after use. In the activated position, the needle cover guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Sol-Care Safety Needle and the BD Eclipse Needles. This included:

1. Label Review
    a. Both devices were similar in design, function and intended use.
    b. Both devices were labeled as EO Sterilized, non pyrogenic, non toxic, single use, latex free and with a five year shelf life.
2. Intended Use Comparison
    a. The intended use for both devices is the same.
3. Material Comparison
    a. Both devices are fabricated from the same materials.

4. Physical, mechanical and biological specifications
    a. A comparison of physical, mechanical and biological specifications showed that the Sol-Care Safety Needles are substantially equivalent to the predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The Sol-Care Safety Needles met the appropriate requirements contained in the following standards:

1. ISO 7864:1993, Sterile Hypodermic Needles for Single Use;

2. ISO 594-2:1998, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment;

3. ISO.9626:1991, Stainless Steel Needle Tubing for Manufacture of Medical Devices;

4. ISO.14971:2009, Medical Devices, Application of Risk Analysis

5. ISO 11135:2007, Medical Apparatus – Epoxy Ethane Sterilization Confirmation and Routine Control

6. 11607-1,-1:2006, Packaging for terminally sterilized medical devices

7. ISO 10993-1:2006, Biological evaluation of medical devices Part 1: Evaluation and testing

8. ISO 23908:2007, Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling"

9. FDA Guidance on the content of premarket notification [510(k)] submissions for hypodermic single lumen needles, April, 1993.

10. Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features. Document Issued on: August 9, 2005

H. Discussion of Clinical Tests:

None submitted

I. Conclusions Demonstrating Safety, Effectiveness and Performance:

The device has been tested and found to meet all product specifications and requirements. Accelerated aging was used to verify the performance of the product over the life of the device.

Instructions for Use detail how to use the devices and the conditions of use. Product labeling clearly shows that the device is for single patient use only.

A Simulated Use Study was conducted with the Sol-Care Safety Needle. The conclusion of the study showed that the Sol-Care Safety Needle is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 8, 2013

Mr. Jim Barley
Director of Regulatory Affairs/Quality Assurance
Sol-Millennium Medical
5415 Sugarloaf Pkwy Suite 2203
Lawrenceville, GA 30043

Re: K123684
Trade/Device Name: Sol-Care Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 31, 2013
Received: February 21, 2013

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

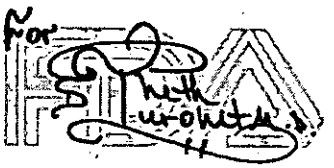
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K123684

Device Name: Sol-Care Safety Needle

Indications For Use:

The Sol-Care Safety Hypodermic Needle is used in conjunction with a standard syringe. This device is used for aspiration and administration of medication.

The Sol-Care Safety Hypodermic Needle safety mechanism covers the needle after use. In the activated position, the needle cover guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123684